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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health/National Institute of Environmental Health Sciences

Proposed collection; comment request

The Sister Study: A Prospective Study of the Genetic and Environmental Risk Factors for Breast Cancer

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Institute of Environmental Health Sciences (NIEHS), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

PROPOSED COLLECTION: *Title:* The Sister Study: A Prospective Study of the Genetic and Environmental Risk Factors for Breast Cancer. *Type of Information Collection Request:* Revision. *Need and Use of Information Collection:* This is to continue the Phase II follow-up of the Sister Study — a study of genetic and environmental risk factors for the development of breast cancer in a high-risk cohort of sisters of women who have had breast cancer. The etiology of breast cancer is complex, with both genetic and environmental factors likely playing a role. Environmental risk factors, however, have been difficult to identify. By focusing on genetically susceptible subgroups, more precise estimates of the contribution of environmental and other non-genetic factors to disease risk may be possible. Sisters of women with breast cancer are one group at increased risk for breast cancer; we would expect at least 2 times as many breast cancers to accrue in a cohort of sisters as would accrue in a cohort identified through random sampling or other means. In addition, a cohort of sisters should be enriched with regard to the

prevalence of relevant genes and/or exposures, further enhancing the ability to detect gene-environment interactions. Sisters of women with breast cancer will also be at increased risk for ovarian cancer and possibly for other hormonally-mediated diseases. From August 2003 through July 2009, we enrolled a cohort of 50,884 women who had not had breast cancer. We estimated that after the cohort was fully enrolled, approximately 300 new cases of breast cancer will be diagnosed during each year of follow-up. Thus far 1,634 participants have reported being diagnosed with breast cancer. *Frequency of Response:* For the remainder of the study, women will be contacted once each year (when not scheduled for "triennial") to update contact information and health status (10 minutes per response); and asked to complete short (75 minutes per response) follow-up interviews or questionnaires ("triennial") every three years. Follow-up and validation of reported incident breast cancer and other health outcomes is conducted under Clinical Exemption CE 2009-09-004. *Affected Public:* Study participants, next-of-kin/proxies. *Type of Respondents:* Participants enrolled in high-risk cohort study of risk factors for breast cancer; next-of-kin/proxies. The annual reporting burden is as follows: *Estimated Number of Respondents:* 50,884 study participants or next-of-kin/proxies. *Estimated Number of Responses per Respondent:* See annualized table below:

Activity	**Estimated Number of Respondents**	**Estimated Responses per Respondent**	**Average Burden Hours per Response**	**Estimated Total Burden Hours Requested**
Annual Updates	33,923	1	10/60	85,654
Triennial Update	16,961	1	1.25	21,202
TOTAL				**26,856**

Average Burden Hours Per Response:42 minutes; and *Estimated Total Annual Burden Hours Requested:* 26,856. The estimated total annualized cost to respondents $537,120 (assuming $20 hourly wage X 26,856). There are no capital, operating, or maintenance costs.

REQUEST FOR COMMENTS: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: ((1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION: To request more information on the project or to obtain a copy of the data collection plans and instruments, contact Dr. Dale P. Sandler, Chief, Epidemiology Branch, NIEHS, Rall Building A3-05, PO Box 12233, Research Triangle Park, NC 27709, or call non-toll free number (919)-541-4668 or E-mail your request, including your address to: sandler@niehs.nih.gov.

COMMENTS DUE DATE: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

August 7, 2012

(Date)

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